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## Japan

### Food and Agricultural Import Regulations and Standards

### Changes to the MRLs for Ethiprole, Orysastrobin and 3 other chemicals

**2008**

**Approved by:**

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**Report Highlights:**

On May 15, 2008, Government of Japan announced proposed changes to the MRLs for Ethiprole, Orysastrobin, Benthiavalicarb-isopropyl, Benfuresate, and Oxolinic Acid. The comment period will close on May 29, 2008. After the given date, MHLW will also notify these proposed changes to the WTO/SPS committee.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Trade Report  
Tokyo [JA1]  
[JA]

**Summary**

The Japanese Ministry of Health Labour and Welfare (MHLW) announced on May 16 proposed changes to the MRLs for Ethiprole, Orysastrobin, Benthialvalicarb-isopropyl, Benfuresate, and Oxolinic Acid. The period for sending comments on these changes ends May 29. If you have comments it is best to send directly to MHLW as soon as possible, however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

The comments can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

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Department of Food Safety,  
Pharmaceutical and Food Safety Bureau,  
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Please also consider copying the U.S. Embassy, Tokyo at [agtokyo@usda.gov](mailto:agtokyo@usda.gov) on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

## Details of Proposed Changes

### Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is going to develop the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just "agricultural chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.\* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has reviewed MRLs for some pesticides which had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established draft MRLs for some food commodities.

This activity is targeted to 5 chemicals: Ethiprole, Orysastrobin, Benthiavalicarb-isopropyl, Benfuresate, and Oxolinic Acid. Details are given below.

*Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.*

### Outline of revision

Ethiprole (insecticide): This chemical is already permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries (MAFF) will expand the scope of target crops for which the use of the chemical is permitted. In response to MAFF's action, the MHLW has comprehensively reviewed the existing MRLs to establish MRLs for the new targets.

Orysastrobin (fungicide): This chemical is already permitted for use in Japan. The MHLW has newly established an MRL (draft) for the "aquatic animals" category.

Benthiavalicarb-isopropyl (fungicide): This chemical is already permitted for use in Japan. MAFF will expand the scope of target crops for which the use of the chemical is permitted. In response to MAFF's action, the MHLW has comprehensively reviewed the existing MRLs to establish MRLs for the new targets.

Benfuresate (herbicide): This chemical is already permitted for use in Japan. The MHLW has reviewed MRLs which had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established an MRL (draft) for the "aquatic animals" category.

Oxolinic Acid (fungicide, synthetic antimicrobial): This chemical is already permitted for use in Japan both as a pesticide and as a veterinary drug. MAFF will expand the scope of target crops for which the use of the chemical is permitted. In response to MAFF's action, the MHLW has comprehensively reviewed the existing MRLs to establish MRLs for the new targets.

For draft MRLs, see Attachments 1-1 through 1-5.

The existing MRLs for the five chemicals appear in either of the MRLs List (the Item 6, Section A "General Compositional Standards for Food," Part I "Food" of the Specifications and Standards for Food, Food Additives, Etc.) or Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. Finalized MRLs for these chemicals will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

Attachment 1-1

## Ethiprole (insecticide)

Commodity	MRL (ppm)	Current MRL (ppm)
Rice (brown rice)	0.2	0.2
Wheat		0.02
Barley		0.02
Rye		0.02
Corn (maize)		0.02
Buckwheat		0.02
Other cereal grains <sup>1</sup>		0.02
Soybeans, dry	0.2	0.02
Beans, dry <sup>2</sup>		0.02
Peas		0.02
Broad beans		0.02
Peanuts, dry		0.02
Other legumes/pulses <sup>3</sup>		0.02
Potato		0.02
Taro		0.02
Sweet potato		0.02
Yam		0.02
Konjac		0.02
Other potatoes <sup>4</sup>		0.02
Sugar beet		0.02
Sugarcane		0.02
Japanese radish, roots		0.02
Japanese radish, leaves		0.02
Turnip, roots		0.02
Turnip, leaves		0.02
Horseradish		0.02
Watercress		0.02
Chinese cabbage		0.02
Cabbage		0.02
Brussels sprouts		0.02
Kale		0.02
Komatsuna, Japanese mustard spinach		0.02
Kyona		0.02
Qing-geng-cai		0.02
Cauliflower		0.02
Broccoli		0.02
Other cruciferous vegetables <sup>5</sup>		0.02
Burdock		0.02
Salsify		0.02
Artichoke		0.02
Chicory		0.02
Endive		0.02
Shungiku		0.02
Lettuce		0.02
Other composite vegetables <sup>6</sup>		0.02

## Ethionazole (Continued)

Commodity	MRL (ppm)	Current MRL (ppm)
Onion		0.02
Welsh (including leek)		0.02
Garlic		0.02
Nira		0.02
Asparagus		0.02
Multiplying onion		0.02
Other liliaceous vegetables <sup>7</sup>		0.02
Carrot		0.02
Parsnip		0.02
Parsley		0.02
Celery		0.02
Mitsuba		0.02
Other umbelliferous vegetables <sup>8</sup>		0.02
Tomato		0.02
Pimiento (sweet pepper)		0.02
Egg plant		0.02
Other solanaceous vegetables <sup>2</sup>		0.02
Cucumber		0.02
Pumpkin		0.02
Oriental pickling melon (vegetable)		0.02
Water melon		0.02
Melons		0.02
Makuwari melon		0.02
Other cucurbitaceous vegetables <sup>10</sup>		0.02
Spinach		0.02
Bamboo shoots		0.02
Okra		0.02
Ginger		0.02
Peas, immature (with pods)		0.02
Kidney beans, immature (with pods)		0.02
Green soybeans	0.5	0.02
Button mushroom		0.02
Shiitake mushroom		0.02
Other mushrooms <sup>11</sup>		0.02
Other vegetables <sup>12</sup>		0.02
Unshu oranges, pulp		0.02
Citrus natsudaidai, whole		0.02
Lemon		0.02
Orange		0.02
Grapefruit		0.02
Lime		0.02
Other citrus fruits <sup>13</sup>		0.02
Apple	1	0.5
Japanese pear		0.02
Pear		0.02
Quince		0.02
Loquat		0.02

## Ethiprole (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Peach		0.02
Nectarine		0.02
Apricot		0.02
Japanese plum		0.02
Mume plum		0.02
Cherry		0.02
Strawberry		0.02
Raspberry		0.02
Blackberry		0.02
Blueberry		0.02
Cranberry		0.02
Huckleberry		0.02
Other berries <sup>14</sup>		0.02
Grape		0.02
Japanese persimmon		0.02
Banana		0.02
Kiwifruit		0.02
Papaya		0.02
Avocado		0.02
Pineapple		0.02
Guava		0.02
Mango		0.02
Passion fruit		0.02
Date		0.02
Other fruits <sup>15</sup>		0.02
Sunflower seeds		0.02
Sesame seeds		0.02
Safflower seeds		0.02
Cotton seeds		0.02
Rapeseeds		0.02
Other oil seeds <sup>16</sup>		0.02
Ginkgo nut		0.02
Chestnut		0.02
Pecan		0.02
Almond		0.02
Walnut		0.02
Other nuts <sup>17</sup>		0.02
Tea	10	10
Coffee beans		0.02
Cacao beans		0.02
Hop		0.02
Other spices <sup>18</sup>		0.02
Other herbs <sup>19</sup>		0.02
Aquatic animals	0.09	

Attachment, 1-2

Orysastrobin (Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.2	0.2
Aquatic animals	0.2	



Attachment, 1-3

## Benthiavalicarb-isopropyl (Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Soybeans, dry	0.05	
Potato	0.02	0.02
Chinese cabbage	2	2
Cabbage	0.05	
Onion	0.02	0.02
Welsh (including leak)	0.7	
Tomato	2	1
Egg plant	2	
Cucumber	0.5	0.5
Melons	0.05	
Grape	2	2

Attachment: 1-4

## Benfluresate (Herbicide)

Commodity	MRL for all uses	Current MRL ppm
Rice (brown rice)	0.05	0.1
Cotton seeds		0.1
Aquatic animals	0.07	

Attachment. 1-5

Oxolinic acid (Fungicide Synthetic antimicrobials)

Commodity	MRL (ppm)	Current MRL (ppm)
Rice (brown rice)	0.3	0.5
Potato	0.3	0.5
Taro		0.5
Sweet potato		0.5
Yam		0.5
Konjac	0.5	0.5
Other potatoes <sup>1</sup>		0.5
Japanese radish, roots	0.05	0.2
Japanese radish, leaves	2	2
Turnip, roots		0.2
Turnip, leaves		2
Horseradish		0.2
Watercress		2
Chinese cabbage	2	2
Cabbage	2	2
Brussels sprouts		2
Kale		2
Komatsuna, Japanese mustard spinach		2
Kyona		2
Qing-geng-oai	2	2
Cauliflower	2	2
Broccoli	0.2	2
Other cruciferous vegetables <sup>2</sup>	2	2
Burdock		0.2
Salsify		0.2
Artichoke		2
Chicory		2
Endive	2	2
Shungiku		2
Lettuce	0.7	2
Other composite vegetables <sup>3</sup>		2
Onion	0.1	0.1
Welsh (including leek)	2	2
Garlic	0.05	0.1
Nira		2
Asparagus	0.7	2
Multiplying onion		2
Other liliaceous vegetables <sup>4</sup>	0.3	2
Carrot	0.2	0.2
Parsnip		0.2
Parsley	2	2
Celery	2	2
Mitsuba		2
Other umbelliferous vegetables <sup>5</sup>		2

## Oxolinic acid (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Spinach		2
Bamboo shoots		0.2
Ginger		0.2
Other vegetables <sup>12</sup>		2
Apple		0.5
Japanese pear	0.3	0.5
Pear	0.3	0.5
Quince		0.5
Peach	0.3	
Nectarine		0.5
Mume plum	20	
Japanese persimmon		0.5
Banana		0.5
Papaya		0.5
Avocado		0.5
Pineapple		0.5
Guava		0.5
Mango		0.5
Passion fruit		0.5
Other spices <sup>18</sup>		2
Other herbs <sup>19</sup>	2	2
Cattle, muscle	0.1	1
Pig, muscle	0.02	1
Cattle, fat	0.05	0.05
Pig, fat	0.02	0.02
Cattle, liver	0.1	1
Pig, liver	0.02	1
Cattle, kidney	0.1	1
Pig, kidney	0.02	1
Cattle, edible offal	0.1	1
Pig, edible offal	0.02	1
Chicken, muscle	0.03	1
Chicken, fat	0.1	0.1
Chicken, liver	0.04	1
Chicken, kidney	0.04	1
Chicken, edible offal	0.06	1
Chicken, eggs		0.05
Other poultry <sup>20</sup> , eggs		0.05
Salmoniformes	0.1	0.05
Anguilliformes	0.1	0.05
Perciformes	0.06	0.06
Other fish <sup>21</sup>	0.05	0.03
Crustaceans	0.03	0.03

## Note:

For Ethiprole, Orysastrobins, Benthiavalicarb-isopropyl, and Benfuresate, the uniform limit (0.01 ppm) will be applied to commodities for which draft MRLs are not given. Some limits in the column, "MRL (draft)," remain unchanged from the current MRLs. For Oxolinic Acid, the provision of Item 1, Section A, Part I of the Specifications and Standards for Food, Food Additives, Etc.\* will be applied to commodities for which draft MRLs are not given. These commodities shall not contain any antimicrobial or synthetic antibacterial after the implementation of this revision. based on

\* Item 1, Section A "General Compositional Standards for Food," Part I "Food" of the Specifications and Standards for Food, Food Additives, Etc. No food shall contain any antimicrobial or synthetic antibacterial, unless the antimicrobial or synthetic antibacterial is designated by the Minister of Health, Labour and Welfare as a food additive unlikely to harm human health, or unless compositional specifications are established for the antimicrobial or synthetic antibacterial in the corresponding food.

Currently, an MRL of 0.02 ppm is set for ethiprole on some crops, instead of the uniform limit (0.01 ppm) because the determination limit of the applicable analytical method was 0.02 ppm at the time of standards setting. By this review, the limit will be modified and the uniform limit will be applied to these crops because the improved method has enabled the determination of ethiprole to the level of 0.01 ppm.

1. "Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.
2. "Beans (dry)" includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.
3. "Other legumes/pulses" refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.
4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.
5. "Other cruciferous vegetables" refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, komatsuna (Japanese mustard spinach), kyona, qing-geng-cai, cauliflower, broccoli, and herbs.
6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, shungiku, lettuce (including cos lettuce and leaf lettuce), and herbs.
7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, nira, asparagus, multiplying onion, and herbs.
8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, mitsuba, spices, and herbs.
9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.

10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and makuwauri melon.
11. "Other mushrooms" refers to all mushrooms, except button mushroom, and shiitake mushroom.
12. "Other vegetables" refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.
13. "Other citrus fruits" refers to all citrus fruits, except unshu orange (pulp), citrus natsudaidei (pulp), citrus natsudaidei (peel), citrus natsudaidei (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.
14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.
15. "Other fruits" refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.
16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.
17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.
18. "Other spices" refers to all spices, except horseradish, wasabi (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), yuzu (Chinese citron) peels and sesame seeds.
19. "Other herbs" refers to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.
20. "Other poultry" refers to all poultry, except chicken.
21. "Other fish" refers to all fish, except salmoniformes, anguilliformes, and perciformes.